

**Notice of Allowability**

Application No.

10/713,438

Examiner

Javier G. Blanco

Applicant(s)

EVANS ET AL.

Art Unit

3738

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Response/Amendment filed July 10, 2006.
2. ☒ The allowed claim(s) is/are 36, 38, 39, 40, 42-44, 46, 47, 51-64, and 69-73.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Javier G. Blanco  
April 12, 2007

## DETAILED ACTION

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Jeffrey Ramberg on April 12, 2007.

Claim 36 (Currently Amended) A conformable, multi-phasic bone implant for the repair and regeneration of bone tissue, said implant consisting of a plastically deformable, tissue conductive matrix for tissue regeneration, said matrix consisting of two phases, wherein a first phase of said matrix consists of ~~a non-soluble fiber material~~ native insoluble collagen fibers and a second phase consists of ~~a flowable biocompatible polymer~~ soluble collagen, said implant having a consistency of a putty just prior to implantation, and remaining at least somewhat compliant after implantation.

Claims 38 (Currently Amended) A conformable, multi-phasic bone implant for the repair and regeneration of bone tissue, said implant comprising components that resorb in stages wherein:

- a. At least a first of said components is a non-soluble ceramic granule;
- b. At least a second of said components is ~~non-soluble collagen fibers~~ native insoluble collagen fibers and

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c. At least a third component is a flowable collagen gel;  
wherein the ceramic granules are blended into the ~~non-soluble collagen fibers~~ native insoluble collagen fibers as an admixture, and wherein the collagen gel holds the admixture of ceramic granules and ~~non-soluble collagen fibers~~ native insoluble collagen fibers together, providing a level of structural integrity to the implant, and further wherein said porous implant is arranged for placement within a body of a living being, and still further wherein said implant is plastically deformable, tissue conductive, has a consistency of a putty just prior to implantation and retains at least some compliance following implantation.

Claim 39 (Currently Amended) A conformable, multi-phasic bone implant for the repair and regeneration of a defect in a bone of a living being, said implant comprising a plurality of components that resorb in stages wherein:

- a. At least a first component of said components is ~~non-soluble collagen fibers~~ native insoluble collagen fibers; and
- b. At least a second component of said components is a flowable soluble collagen gel; wherein said porous implant is arranged for placement in a body of said living being, further wherein the implant is plastically deformable, tissue conductive, has a consistency of a putty just prior to implantation and retains at least some compliance following implantation, and further wherein the flowable soluble collagen gel is mixed with the ~~non-soluble collagen fibers~~ native insoluble collagen fibers and holds the ~~non-soluble collagen fibers~~ native insoluble collagen fibers together, providing a level of structural integrity to

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the implant.

Claim 43 (Currently Amended) A conformable, multi-phasic bone implant for the repair and regeneration of a defect in a bone of a living being, said implant comprising a plastically deformable, tissue conductive matrix for tissue regeneration, said matrix comprising at least two phases, wherein at least a first phase of said matrix comprises ~~a non-soluble fiber material~~ native insoluble collagen fibers and at least a second phase comprises a flowable biocompatible polymer comprising soluble collagen, further wherein said porous implant is suitable for placement within a body of said living being, said implant having a consistency of a putty just prior to implantation, and remaining at least somewhat compliant after implantation.

Claim 45 has been cancelled.

Claim 48 has been cancelled.

Claim 49 has been cancelled.

Claim 72 (Currently Amended) The implant of claim 38, wherein said ~~non-soluble collagen fibers~~ native insoluble collagen fibers do not consist of collagen fibrils at the highest level of structural organization.

Claim 73 (Currently Amended) The bone implant of claim 39, wherein said ~~non-soluble collagen fibers~~ native insoluble collagen fibers do not consist of the fibrillar form of collagen at the highest level of structural organization.

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Claim 74 has been cancelled.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

April 12, 2007



CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700